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09/846,722	05/01/2001	Stanley E. Katz	CSI 1.0-005CIP	8104
7590	07/17/2006		EXAMINER	
RICHARD R. MUCCINO 758 Springfield Avenue Summit, NJ 07901				CHONG, YONG SOO
		ART UNIT	PAPER NUMBER	1617

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/846,722

Filing Date: May 01, 2001

Appellant(s): KATZ ET AL.

Richard R. Muccino
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/27/2006 appealing from the Office action mailed 11/30/2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Katz et al. (US Patent 5,798,388)

Amschler et al. (US Patent 5,449,676)

Geria et al. (US Patent 5,478,565)

Picciano et al. (US Patent 5,897,872)

(9) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-17 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz (US Patent 5,798,388) in view of Amschler et al. (US Patent 5,449,676).

Katz teaches a method of treating a disease state in mammals caused by mammalian cells involved in the inflammatory response, which comprises contacting the mammalian cells involved in the inflammatory response with a therapeutically effective amount of an inflammatory mediator (col. 4, lines 58-67). The inflammatory mediators are taught to be antioxidants selected from pyruvates (including lithium pyruvate, sodium pyruvate, potassium pyruvate, etc.) and pyruvate precursors, such as pyruvyl-glycine, pyruvyl-alanine, pyruvyl-leucine, pyruvyl-valine, etc. (col. 7, lines 21-41). The inflammatory response reduced by the treatment is taught to be at least one of oxygen

radical production, peroxide production, cytokine and/or protease production, prostaglandin production, erythema, histamine and interleukin production (col. 7, lines 15-20). Administration of the composition is in the form of liquids, ointments, etc. (col. 7, lines 52-56). Additional therapeutic agents, such as antibacterials, antivirals, antifungals, antihistamines, proteins, enzymes, hormones, nonsteroidal anti-inflammatories, cytokines and steroids, are taught to be administer prior to, after and/or with the inflammatory mediator (col. 8, lines 13-18). It is noted that while administration is taught for "injured cells" in general, the reference specifically teaches inhalation treatments for disorders such as bronchial asthma, bronchitis, etc. (col. 6, line 66-col. 7, line 10; col. 7, line 65-col. 8, line 12). Katz does not specifically teach the administration of the composition to the nasal cells nor does Katz specifically teach the concentration of inflammatory mediator as herein claimed.

Amschler et al. teaches a method of treating inflammatory disorders of the lung (e.g. bronchitis, bronchial asthma, etc.) and inflammatory disorders of the nose (e.g. rhinitis, sinusitis, etc.) with an anti-inflammatory composition (col. 8, lines 36-57; col. 9, lines 61-68).

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the composition of Katz to the nasal or sinus cavities for the treatment of inflammatory disorders of the nasal or sinus cavities, such as rhinitis or sinusitis because (1) Katz teaches the treatment of mammalian cells involved in a inflammatory response with an anti-inflammatory composition, in general; (2) Katz teaches the treatment of inflammatory disorders such as bronchitis and bronchial

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asthma, specifically; and (3) Amschler et al. teaches that anti-inflammatory compositions are known in the art to treat inflammatory disorders of the nose, such as rhinitis and sinusitis, and that it is known in the art to treat inflammatory disorders of the lung in a similar manner to those of the nose. One would have been motivated to treat inflammatory disorders of the nose in the manner disclosed by Katz because of an expectation of success in treating a specific inflammatory disorder in a manner taught to be beneficial, generally, by Katz.

It would have been obvious to one of ordinary skill in the art to utilize the concentration of inflammatory mediator in a formulation as instantly claimed because Katz teaches the administration thereof in general and teaches that a formulation should comprise a therapeutically effective amount. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katz and Amschler et al. as applied to claims 1-6, 8-17 and 31 above, and further in view of Geria (US Patent 5,478,565).

Katz and Amschler et al. apply as disclosed above. The references lack a specific teaching of oxymetazoline.

Geria teaches that oxymetazoline is known for the treatment of rhinitis and sinusitis, particularly with the congestion associated therewith (col. 4, lines 1-15).

It would have been obvious to one of ordinary skill in the art to utilize oxymetazoline as the optional therapeutic agent of Katz because (1) Katz teaches that additional therapeutic agents may be utilized in addition to the inflammatory modulators disclosed therein; (2) the combined references render a treatment of rhinitis or sinusitis obvious; (3) oxymetazoline is taught by Geria as known in the art to be useful for the treatment of both rhinitis and sinusitis; and (4) "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). It is noted that the skilled artisan would have been further motivated to add the oxymetazoline to the treatment of the combined references because of an expectation of success of providing, in addition to the reduction of the inflammatory response effectuated by the inflammatory modulator of Katz, congestion relief to the patient suffering from sinusitis or rhinitis.

Claim 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz and Amschler et al. as applied to claims 1-6, 8-17 and 31 above, and further in view of Picciano (US Patent 5,897,872).

Katz and Amschler et al. apply as disclosed above. The references lack a specific teaching of the preferred solution formulation.

Picciano teaches the treatment of sinusitis with an isotonic buffered nasal saline solution comprising water, sodium chloride, 0.65% by weight, iodine, buffer and a

preservative (col. 4, lines 52-59). Sodium bicarbonate, disodium phosphate/sodium phosphate and monobasic potassium phosphate/sodium hydroxide are taught as buffers (col. 4, lines 62-65). Phenylcarbinol, benzalkonium chloride and thimerosal are taught as preservatives (col. 4, lines 65-67). The solution is taught to alleviate congestion and to provide moisturization (col. 4, lines 52-59).

It would have been obvious to one of ordinary skill in the art to treat a patient suffering from sinusitis with the inflammatory modulators of the combined references in the solution of Picciano because (1) Katz teaches the formulation of the compositions disclosed therein as formulated in solutions, in general; (2) the combined references render a method of treating sinusitis with inflammatory modulator compositions obvious; (3) Picciano teaches a solution which is, itself, useful for treating sinusitis; and (4) "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). It is noted that the skilled artisan would have been further motivated to add utilize the solution of Picciano as the solution for the administration of the inflammatory modulators of the combined references because of an expectation of success of providing, in addition to the reduction of the inflammatory response effectuated by the inflammatory modulator of Katz, both congestion relief and nasal moisturization to the patient suffering from sinusitis.

(10) Response to Argument

Appellant argues that inflammatory disorders in the lung are very different from the treatment of inflammatory disorders of the nose and sinuses, because of different cell types and routes of metabolism. This argument is not persuasive. It is noted that Katz teaches a treatment of a disease state in a mammal caused by mammalian cells involved in the inflammatory response. There is no suggestion that this treatment is limited to the exemplification of the treating of inflammatory disorders of the lung exemplified therein. Nonetheless, it makes no difference whether the cell types or route of metabolism is different because a general treatment of mammalian cells involved in an inflammatory response with an anti-inflammatory composition is disclosed.

Appellants even admit that, "At best, *Amschler et al.* may teach that 3-amino-6-arylpyridazine compounds may be used to treat inflammatory disorders both in the lung and in the nose but *Amschler et al.* certainly does not teach that ALL compounds known to treat inflammatory disorders in the lung may be used in similar manner to treat inflammatory disorders in the nose." This is not persuasive because the teachings of Katz are not limited to the treatment of inflammatory disorders of the lung. Examiner also notes that not ALL compounds disclosed by *Amschler et al.* need to teach treatment of inflammatory disorders in the nose. The standard for obviousness is not absolute but simply a reasonable expectation of success. It is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to a person of ordinary skill in the art. *In re*

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Boe, 355 F.2d 961, 148 USPQ 507 (CCPA 1966); *In re Lamberti*, 545 F.2d 747, 19USPQ 279 (CCPA 1976); *In re Fracalossi*, 681 F.2d 792, 215 USPQ 569 (CCPA 1982); *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983).

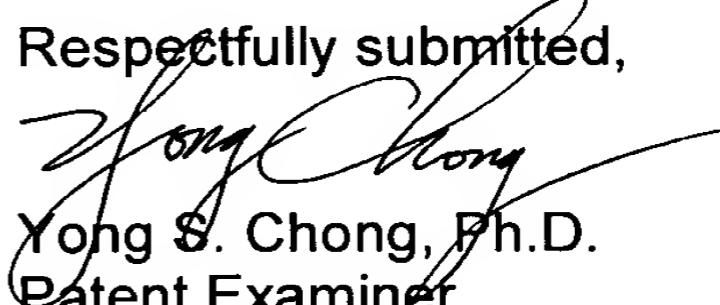
Accordingly, the skilled artisan, when examining the general teaching of Katz with the teaching of Amschler et al. that the inflammatory agents disclosed therein are known to be useful for both the treatment of inflammatory disorders of the lung and nose, would have been motivated by an expectation of success in treating inflammatory disorders of the nose with the methods and compositions of Katz et al. Furthermore, it is pointed out that the compositions administered by both Katz and Amschler et al. are both anti-inflammatory agents. Therefore, it is Examiner's position that a *prima facie* case of obviousness has been established.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,


Yong S. Chong, Ph.D.
Patent Examiner
Art Unit 1617

ysc
July 4, 2006

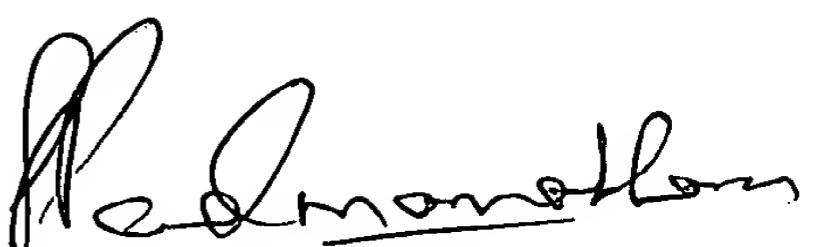
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